ISO 13485:2016

Medical Devices

Internal Auditing

Course Information

Course Name	ISO 13485:2016 – Internal Auditing
Course Designer	World Wide Industrial and Systems Engineers
Course Category	Medical Devices
Course Duration	3 Days
Cost of Course	Refer to Training Schedule

Course Overview

This ISO 13485 Internal Auditor training course will increase awareness of the ISO 13485 medical device standard criteria from the standpoint of an auditor Learn the ideas and methods of conducting successful quality management system process audits in compliance with ISO 13485:2016 and ISO 19011:2011 standards. After finishing this course, you will be able to create an ISO 13485-compliant internal audit system.

ISO 13485:2016 – Medical Devices

Who Should Attend?	• Medical device quality professionals interested in conducting first-party, second party, and/or third-party audits • Management representatives • Quality directors, managers, and engineers • Consultants • Beneficial for those involved in developing, maintaining and implementing an internal audit system.
Course Objectives	By the end of the course, the learner will be able to: • explain the structure and scope of ISO 13485:2016 and how it applies to the organization seeking regulatory compliance • identify the key principles of auditing and auditor responsibilities • plan an internal audit • conduct an effective audit based on process identification, sampling and questioning • determine if corrective action has been effectively implemented
Benefits	• Maintain ISO 13485:2016 compliance • Improve an international benchmark in quality standards • Have confidence that your organisation can rely on qualified auditors • Encourage employees to participate in CPD and ensure that internal regulatory requirements are followed • Produce accurate audit reports and make recommendations for remedial measures.

Course Content

Course Modules	1. Introduction to ISO 13485:2016 2. A Overview of ISO 13485:2016 Requirements 3. Implementation Phases of the ISO 13485 Frameworks 4. Conducting an ISO 13485 Certification Audit 5. The Relationship Between ISO 13485 and ISO 9001 6. Internal Auditing 7. The Internal Audit Plan 8. The Audit Process 9. Internal Audit Evidence and Findings 10. Roles and Responsibilities 11. Resource Management and Product Realisation
Certification	• Certificate of competence. • Certificate of attendance.

Assessments	• If applicable, there will be an assessment at the end of the course. • Delegates have to complete the assessment with a minimum score of 60% to receive a certificate of competence. • Delegates who score between 40% and 59% will get a second attempt at the assessment. • Delegates who score lower than 40% or fail the second attempt, will need to repurchase the course. • Delegates will receive an attendance certificate regardless of a pass or fail.

About WWISE

Who are we?	World Wide Industrial & Systems Engineers (WWISE) is an ISO consultancy, training, business solutions and systems implementation firm based in Southern Africa that provides clients with effective business processes and Safety, Health, Environmental, Risk and Quality (SHERQ) management solutions in preparation for ISO compliance. The solutions we provide and implement allow our clients to compete favourably in modern competitive business environments, locally and internationally. We also strive to be the leading training providers in SHERQ, ISO, Engineering, Finance, Business and Project Management.
What do we do?	Our services are aimed at the improvement of quality, efficiency, knowledge, and competitiveness of client companies. The service range includes: • ISO and SHERQ Systems implementation services whereby we assist client companies in meeting the requirements of ISO 9001, 14001, 22000, 31000, 27001, 20000-1, 50001 and ISO 45001 standards. • Integrated Management Systems development whereby we integrate several business systems and quality management solutions into a single management system to comply with various quality and safety standards. • Training of all employees (Shop Floor to Executive Management) in the fields of SHERQ, Engineering, Finance, Business and Project Management to meet the job responsibilities and expertise requirements of International Standards. • ISO, Legal auditing which includes gap analysis audits, product, process, procedural, and systems auditing by our registered SAATCA auditors.

	• Customised web-based solutions integrating current systems to be in line with ISO requirements We are a Level 1 BBBEE Contributor that specialises in systems development, consultancy, training, and auditing.